Express Mail Label No. EL209599009US
U.S. National Phase Entry of PCT/GB00/01118
"Polycationic Carbohydrates as Immunostimulants in Vaccines"
Filed: 20 September 2001
PRELIMINARY AMENDMENT

Version with markings to show changes made

- 4. (Amended) A pharmaceutical composition comprising a biologically active agent which is capable of generating a protective immune response in an animal, and a polycationic carbohydrate according to [any one of] claim[s] 1 [to 3].
- 6. (Amended) A pharmaceutical composition according to claim 5 which comprises particles comprising
- (i) a biologically active agent which is able to produce an immune response in an animal to which it is administered;
 - (ii) a first material capable of forming particles; and
 - (iii) a polycationic carbohydrate according to [any one of] claim[s] 1 [to 3].
- 10. (Amended) A composition according to claim 9 wherein the chitin derivative is chitosan, chitosan chloride, or chitosan glutamate or a polycationic carbohydrate according to claim 2 [or claim 3].
- 11. (Amended) A composition according to [any one of] claim[s] 6 [to 10] wherein the particle comprises microspheres, microparticles or liposomes.

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- 13. (Amended) A composition according to [any one of] claim[s] 6 [to 12] wherein the first material is a polymeric material which has a molecular weight of 100kDa or more.
- 14. (Amended) A composition according to [any one of] claim[s] 6 [to 13] wherein the first material comprises poly-(L-lactide).
- 15. (Amended) A composition according to [any one of] claim[s] 6 [to 14] wherein the ratio of the first material to the polycationic carbohydrate is from 99:1 to 9:1 w/w.
- 16. (Amended) A composition according to [any one of] claim[s] 6 [to 15] wherein the biologically active agent is capable of generating a protective immune response against tetanus, diptheria, or *Yersinia pestis*.
- 18. (Amended) A composition according to [any one of] claim[s] 6 [to 17] which is adapted for intranasal application.
- 19. (Amended) A composition according to [any one of] claim[s] 6 [to 17] which is adapted for parenteral administration.

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- 20. (Amended) A composition according to [any one of] claim[s] 6 [to 19] which further comprises a chemical compound selected from
 - (A) a polyamino acid,
 - (B) a vitamin or vitamin derivative,
 - (C) cationic pluronics,
 - (D) a clathrate,
 - (E) a complexing agent,
 - (F) cetrimides[;],
 - (G) an S-layer protein; or
 - (H) methyl-glucamine.
- 23. (Amended) A method for producing a pharmaceutical composition, which method comprises encapsulating a biologically active agent in a first material, in the presence of a polycationic carbohydrate according to [any one of] claim[s] 1 [to 3].
- 30. (Amended) A method of protecting an animal against a pathogen, said method comprising administering to said animal, a protective agent which is able to stimulate the animal's immune system to produce a response which is protective against said pathogen, and an immunostimulant comprising a polycationic carbohydrate according to [any one of] claim[s] 1 [to 3].

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- 31. (Amended) A method of protecting an animal against a pathogen, said method comprising administering to said animal, a protective agent which is able to stimulate the animal's immune system to produce a response which is protective against said pathogen, in the form of a composition according to [any one of] claim[s] 6 [to 22].
- 32. (Amended) A method according to claim 30 [or claim 31] wherein the protective agent which is able to stimulate the animal's immune system to produce a response which is protective against said pathogen, and an immunostimulant comprising a polycationic carbohydrate is applied parenterally or to a mucosal surface.
- 35. (Amended) The use of a polycationic carbohydrate or a pharmaceutically acceptable derivative thereof according to [any one of] claim[s] 1 [to 3] as an immunostimulant, in the preparation of a vaccine for use in prophylactic or therapeutic treatment.